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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61L 2/02, 2/18

A1

(11) International Publication Number: **WO 99/58164**

(43) International Publication Date: 18 November 1999 (18.11.99)

(21) International Application Number: PCT/US99/09474

(22) International Filing Date: 28 April 1999 (28.04.99)

(30) Priority Data:
09/076,642 12 May 1998 (12.05.98) US

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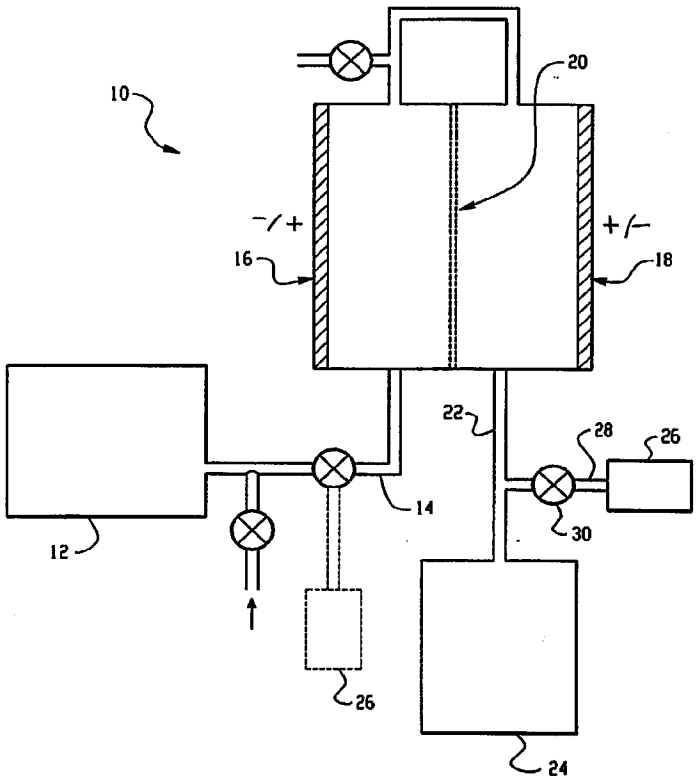
(81) Designated States: AU, CA, CN, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: ADDITIVES FOR ELECTROCHEMICALLY ACTIVATED SOLUTIONS TO MINIMIZE CORROSION

(57) Abstract

A composition for minimizing corrosivity and increasing penetration of electrochemically activated sterilizing and disinfecting solutions includes a buffering system, a corrosion inhibitor, a surfactant, and a chelator. The buffering system maintains the electrochemically activated solution at an optimal pH for microorganism kill while the surfactant improves sterilant penetration of medical instruments and the like which are to be sterilized or disinfected by the electrochemically activated solution. The composition reduces corrosion of the instruments without impairing the capacity of the electrochemically activated solution to destroy microorganisms.



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ADDITIVES FOR ELECTROCHEMICALLY ACTIVATED SOLUTIONS TO MINIMIZE CORROSION

Background of the Invention

The present invention relates to the sterilization and disinfection arts. It finds particular application in conjunction with electrochemically activated solutions containing chlorine species for sterilization or disinfection of medical and pharmaceutical equipment, and will be described with particular reference thereto. It should be appreciated, however, that the invention is also applicable to other sterilization, disinfection, and sanitization methods employing oxidizing species such as chlorine-containing bleach solutions.

The reusability of medical instruments has become increasingly important in an effort to provide cost-effective health care. Many of the instruments that are now sterilized or disinfected, such as endoscopes, contain tortuous paths, narrow lumens, and other difficult to clean areas.

Recently, electrochemically activated sterilant and disinfectant solutions produced from brine have been developed for decontamination of medical instruments and the like. Active sterilizing and disinfecting species, such as hypochlorite, are generated by electrolysis of a salt solution, such as brine (a solution of sodium chloride in water). Electrolysis devices are known which receive a supply of the salt solution and produce anolyte and catholyte solutions at an anode and a cathode, respectively. The anolyte and catholyte may be used individually or as a combination. The anolyte has been found to have anti-microbial properties, including anti-viral properties. The catholyte has been found to have cleaning properties.

To create these anolyte and catholyte solutions, the salt solution is passed through an electrolytic unit or module which has at least one anode chamber and at least one cathode chamber which may be separated from each other by a membrane. An anode contacts the solution flowing through the anode chamber, while a cathode contacts the solution flowing through the cathode chamber. The membrane generally allows the transfer of charged species between the anode and the cathode but limits fluid transfer between the anode and cathode chambers. The salt solution undergoes oxidation in the anode chamber and reduction in the cathode chamber. The anolyte and catholyte solutions are used separately or in combination for a wide variety of different purposes.

The activity of solutions produced from brine is often expressed in terms of the concentration of active, or "free" chlorine species. Typically, a free chlorine concentration (the concentration of active chlorine species measured) of 200 to 2000 ppm is employed for sterilization, while disinfection is carried out at concentrations of 2 ppm and above. Instruments are sterilized or disinfected by immersing them for a predetermined period of time in the activated solution. These solutions are capable of effecting fairly rapid disinfection or sterilization, without leaving harmful or unsightly deposits on the instruments. Moreover, the disinfectant or sterilant is generated only as it is required, thereby avoiding the need for storing potentially hazardous sterilants.

However, because of the corrosive nature of the electrochemically activated solutions, metal parts of the instruments, such as those made of aluminum, copper, brass, and stainless steel, have a tendency to corrode when repeatedly exposed to the solutions. Joints in the instruments, where different metals are in contact, tend to corrode more readily. Because medical instruments are designed to be reused many times during their expected lifetimes, even a fairly small corrosive effect can cause significant damage to the instruments with repeated contact.

Moreover, it is often undesirable for poorly adhered corrosion products to remain on the instruments. These deposits may be released subsequently from the instruments and cause contamination when the instruments are used.

Medical instruments frequently include components which provide a challenge to the penetration of the disinfectant or sterilant solution. Endoscopes, for example, have long narrow tubes which slow the movement of the decontaminant, while hinges and other joints provide semi-enclosed areas through which the passage of decontaminant is reduced. These areas may prevent decontamination or increase the time for decontamination to be assured. Longer decontamination times increase the opportunity for corrosion of the instruments and reduce the throughput of instruments through a decontamination system. Electrochemically activated solutions tend to have high surface energies which have been found to make penetration more difficult.

There remains a need for a composition for addition to an electrochemically activated solution which minimizes the corrosion of items to be sterilized or disinfected and which penetrates all areas of the items for complete and rapid sterilization or disinfection.

The present invention provides a new and improved composition for use in electrochemically activated solutions which overcomes the above referenced problems and others.

Summary of the Invention

In accordance with one aspect of the present invention, a composition for minimizing corrosivity and improving penetration of an electrochemically activated sterilizing or disinfecting solution, without appreciably lowering the rate of kill of microorganisms, is provided. The composition is characterized by a buffering system for buffering the pH of the electrochemically activated solution to a pH of between about 5.0 and about 9.0, a corrosion inhibitor, a non-ionic surfactant which is stable in the electrochemically activated solution, and a chelator.

In accordance with another aspect of the present invention, a method of sterilization or disinfection is provided. The method is characterized by generating an electrochemically activated sterilant or disinfectant solution which includes the composition described above, and immersing items to be sterilized or disinfected in the solution.

In accordance with yet another aspect of the present invention, a sterilizing or disinfecting system is provided. The system comprises a source of a salt solution and a generator for generating a sterilant or disinfectant solution from the salt solution. The sterilant or disinfectant solution includes active sterilant species. The system further comprises an inlet line, which fluidly connects the source of the salt solution to the generator, a sterilization or disinfection vessel, and an outlet line, which fluidly connects the generator to the vessel for transporting the sterilant or disinfectant solution to the vessel. The system is characterized by a dispenser for dispensing the composition described above into the salt solution or the sterilant solution.

In accordance with another aspect of the present invention, a sterilizing or disinfecting solution is provided. The solution comprises active chlorine species, and is characterized by a composition as described above.

One advantage of the present invention is that it enables medical instruments to be disinfected sterilized or disinfected repeatedly with minimal corrosion or degradation of the instruments.

Another advantage of the present invention is that sterilant or disinfectant penetrates instruments more readily, thereby improving the effectiveness of the sterilant or disinfectant and increasing the kill rate.

Still further advantages of the present invention will become apparent to those of ordinary skill in the art upon reading and understanding the following detailed description of the preferred embodiments.

Brief Description of the Drawings

The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating a preferred embodiment and are not to be construed as limiting the invention.

FIGURE 1 is a schematic diagram of a preferred embodiment of a sterilization or disinfecting system of the present invention.

Detailed Description of the Preferred Embodiments

Compositions for incorporating into electrochemically activated sterilant or disinfectant solutions according to the present invention include a buffering system, a corrosion inhibitor, a surfactant, and a chelator. The composition reduces corrosion of medical instruments and the like that are sterilized or disinfected in the sterilant or disinfectant solutions and also reduces corrosion of sterilization or disinfection equipment. It is to be understood that the compositions described herein are not limited to incorporation into sterilant solutions but are also applicable to disinfectant solutions. For ease of reference, however, the use of the compositions in sterilant solutions for sterilization will often be referred to, with the understanding that the sterilization-related terms should be read as encompassing the use of the compositions in disinfectant solutions for disinfection.

The surface tension of the sterilant solutions is reduced significantly by addition of the composition, leading to improved contact of the sterilant with the surfaces of the instruments, increased penetration of the instruments, and improved penetration of the cell walls of microorganisms. The compositions improve the kill rate of microorganisms by the sterilant solutions. Typically, the composition is added to the sterilant solution after electrochemical generation of the active sterilant species, although addition prior to activation is also feasible. The

composition is stable in the electrochemically activated solution at temperatures conventionally used for sterilization or disinfection over periods of time in excess of those generally used. (Sterilization is generally carried out at around 50 °C, for about 12-60 minutes. Disinfection is typically effected in a shorter period of time.)

The buffering system buffers the sterilant solution to a pH of about 5 to about 9. A pH in this range provides for effective kill of microorganisms typically found on medical instruments by the sterilant. Preferably the pH is selected within the range to minimize corrosion of instruments. The optimal pH for minimizing corrosion is dependent, to some degree, on the composition of metals used in the medical instruments. The buffering system preferably buffers the solution to a pH within the range which is least corrosive to the instruments typically sterilized or disinfected. For most instruments, a pH of between 5 and 9 is preferred. A preferred buffering system includes at least one, and more preferably, a combination of alkali metal phosphates, from the group including mono- and di- alkali metal phosphates, hexametaphosphates, and tripolyphosphates. The combination of phosphates selected depends on the desired pH. Monosodium phosphate, for example, buffers the solution to an acidic pH, while disodium phosphate buffers to a basic pH. Tripolyphosphates, although exhibiting some buffering power, are not sufficiently strong buffers to provide effective buffering alone. Thus, they are used in combination with one or more of the other phosphate buffers in the buffering system. By selecting a combination of phosphates, the pH is adjusted to the desired pH. The alkali metal in the phosphate salt is preferably sodium or potassium. Combinations of sodium and potassium salts are optionally used. Optionally, the buffering system includes sulfates such as sodium sulfate. When selected as a component of the buffering system, the phosphates and sulfates are preferably present in the following concentration ranges by weight:

Monosodium phosphate	0.01-0.5%
Disodium phosphate	0.01-5.0%
Sodium hexametaphosphate	0.01-5.0%
Tripolyphosphates	0.01-5.0%
Sodium sulfate	0.01-5.0%

The corrosion inhibitor inhibits corrosion of the items to be sterilized or disinfected by the electrochemically active solution. Mono- and di- alkali metal phosphates and hexametaphosphate, used as buffers in the concentration ranges noted above, are conveniently also used as inhibitors. Alternatively, other corrosion inhibitors known in the art are used, such as sodium benzotriazole, either alone, or in combination with the above-mentioned phosphates. The corrosion inhibitor, however, is one which does not significantly reduce the ability of the electrochemically activated solution to destroy microorganisms.

The surfactant is one that reduces the surface tension of the sterilant solution. Electrochemically activated solutions were analyzed and found to have surface tensions of around that of deionized water, or slightly less (64.1-72.8 dynes/cm for the electrochemically activated solutions tested. Deionized water has a surface tension of around 72.8 dynes/cm at 25 °C). Preferably, the surface tension of the electrochemically activated solution is lowered by the composition to around 30-35 dynes/cm or below. Surface tensions of 28.0-28.7 dynes/cm were readily achieved for electrochemically activated solutions containing compositions of the present invention. Preferred surfactants are non-ionic surfactants from the group consisting of fatty alcohol polyglycol ethers, nonylphenoxypoly(ethyleneoxy)ethanol, and ethoxylated polyoxypropylene. Other non-ionic, cationic, and anionic surfactants are optionally included in the composition. The surfactant is preferably one that is stable in the electrochemically activated solution. If the composition is

to be added to the sterilant solution prior to electrochemical generation of the active species, the surfactant is one which is not degraded significantly when it passes the electrodes of a generator. Optionally, more than one surfactant is used in the composition.

When present in the composition, the surfactants are preferably present in the following concentrations by weight:

Fatty alcohol polyglycol ethers	0.01-1.0%
Nonylphenoxypoly(ethyleneoxy)ethanol	0.0001-0.5%
Ethoxylated polyoxypropylene	0.0001-0.5%

Preferred chelators are those which are stable in the electrochemically activated solution and include hexametaphosphate, tripolyphosphates and sodium nitriloacetic acid. These chelators are stable in electrochemically activated solutions over extended periods and are effective chelators for organic loads and removing water hardness. Preferably, the composition includes a combination of chelators. Sodium polyacrylates are particularly preferred chelators. Tripolyphosphates are also desirable because of their other beneficial properties, including buffering, surfactant, and detergent properties. Sodium nitriloacetic acid is advantageous, but may pose environmental concerns in some circumstances. A number of conventional chelators are less suited to use in the sterilant solutions because they render the composition unstable in the solutions. One such chelator is ethylenediaminetetraacetic acid (EDTA).

When present in the composition, the chelators are preferably present in the following concentration ranges by weight:

Tripolyphosphates	0.01-5.0%
Hexametaphosphate	0.01-5.0%
Sodium polyacrylates	0.01-0.5%
Sodium nitriloacetic acid	0.01-0.5%

Optionally, the composition also includes a detergent. While medical instruments are expected to be cleaned prior to sterilization or disinfection in an electrochemically activated solution, incomplete cleaning results in the presence of biological materials on the instruments. These materials tend to reduce the effectiveness of the sterilant or disinfectant, for example, by providing a physical barrier to the passage of sterilant to the surfaces of the instruments. Tripolyphosphates are preferred detergents because of their other beneficial properties, including buffering, surfactant, and chelation properties. When present in the composition, the detergents are preferably at a concentration of 0.01-5.0%.

When hard water is used in the preparation of the electrochemically activated solution, the phosphates used in the composition tend to cause calcium and magnesium salts present in the hard water to precipitate and coat the instruments being decontaminated. A sequestering agent appropriate to prevent precipitation, such as sodium hexametaphosphate is preferably provided.

To sterilize or disinfect medical, dental, surgical, or mortuary instruments, devices, implants and the like, active chlorine species are generated electrochemically in a solution containing brine. Typically, a free chlorine concentration of about 200 to about 2000 ppm. provides an effective sterilant. A concentration of about 2 ppm. or above is effective as a disinfectant.

The composition is added to the electrochemically activated solution, either before, during, or after generation of active chlorine species. Preferably, a solution of the composition in water is metered into the sterilant solution until a desired concentration is reached.

Instruments to be sterilized or disinfected are preferably washed in a detergent solution prior to sterilization or disinfection, to remove substantially all of the organic materials and other dirt deposited on the instruments during use. The instruments are then immersed

in the sterilant or disinfectant solution for a period sufficient to effect sterilization or disinfection. The instruments are typically rinsed and dried before storing and subsequent reuse.

With reference to FIGURE 1, a sterilization or disinfection system provides for generation of an electrochemically active solution which includes the composition and for sterilization or disinfection of medical instruments and the like. The system includes an electrochemically activated solution generator, such as an electrolytic cell, **10**. An inlet line **14** directs a salt solution, such as brine, from a source of the salt solution **12** into the generator. Active sterilant species are generated electrochemically in the salt solution by application of a voltage across electrodes **16** and **18** within the generator. A membrane **20**, formed from a micro-porous or selective ion transport material, separates anolyte and catholyte streams generated from the salt solution by the generator. An outlet line **22** carries the sterilant solution containing the active species, typically the anolyte stream, from the generator to a vessel **24** for disinfection or sterilization of the instruments.

A dispenser **26** dispenses the composition into the system, preferably as a solution in water, to achieve the desired concentration of composition additives in the vessel. The composition is conveniently added to the sterilizing solution through an additive inlet line **28** which is connected to the vessel **24** by a valve **30**. However, other means of addition which provide the desired additive concentrations within the sterilization vessel are also contemplated, such as addition of the composition to the brine. Optionally, the composition additives are added separately.

Examples

Compositions were prepared according to the following formulation:

One or more of the following buffer/detergent/ corrosion inhibitors:

Monosodium phosphate	0.01-0.5%
Disodium phosphate	0.01-5.0%
Sodium hexametaphosphate	0.01-5.0%
Sodium sulfate	0.01-5.0%

One or more of the following non-ionic surfactants:

Fatty alcohol polyglycol ethers	0.01-1.0%
Nonylphenoxypoly(ethyleneoxy)ethanol	0.0001-0.5%
Ethoxylated polyoxypropylene	0.0001-0.5%

One or more of the following chelators:

Sodium hexametaphosphate	0.01-5.0%
Sodium polyacrylates	0.01-0.5%
Tripolyphosphates	0.01-5.0%
Sodium nitriloacetic acid	0.01-0.5%

The compositions were found to provide or generate stable solutions containing free chlorine species at concentrations in the range of 100 to about 2000 ppm free chlorine. No degradation of the compositions was observed over a 24 hour period.

Example 1

An electrochemically activated solution including the composition was prepared with the following formulation:

Disodium phosphate	4.766 g/l
Monosodium phosphate	0.400 g/l
Sodium hexametaphosphate	0.330 g/l
Genapol (fatty alcohol polyglycol ether)	0.400 g/l (462 μl)

The surface tension of the electrochemically activated solution with the composition present was 28.0 dynes/cm. The pH was 7.73 and the free chlorine concentration was 273

ppm. The kill rate of electrochemically activated solutions both with and without the Example 1 composition were compared on samples of *Bacillus subtilis* containing a known population of microorganisms at 20 °C. As shown in Table 1 below, the compositions did not reduce the ability of the solution to destroy microorganisms. The kill rate, expressed in terms of average linear regression D-value (a measure of the time required to reduce the population by 1 log) was not measurably decreased in the solution containing the composition.

Table 1

Test Solution	No. of trials	D-value (sec)	Longest Endpoint (sec)
Electrochemically activated solution	7	28.4±6.6	240
Electrochemically activated solution + composition	1	33.0	210

Example 2

Samples of metals typically used in medical instruments were subjected to repeated cleaning cycles in electrochemically activated solutions both with and without the composition of Example 1. One hour of exposure to the solution was used as a measure of one cleaning cycle. The results, shown in Table 2, indicate that the composition reduces the corrosivity of the electrochemically activated solution towards brass and stainless steel. Parts taken from medical instruments, such as screws, nuts, and an inlet/outlet port, also showed reduced or absence of corrosion after exposure to the electrochemically activated solution with the composition added.

Table 2

	Electrochemically Activated Solution Without Composition		Electrochemically Activated Solution With Composition	
Material	**No. of Cycles**	**Result**	**No. of Cycles**	**Result**
Anodized Aluminum	720	no change	24	no change
Brass	24	~50% surface corrosion	24	~5-10% surface corrosion
Stainless Steel 17-4PH	24	<5% surface corrosion; pitting (~3mm diam.)	24	~2% surface corrosion
Stainless Steel 316L	24	<10% surface corrosion	24	~2% surface corrosion
Parts				
screw with wide threads	120	40% surface corrosion	120	no change
screw with narrow threads	72	<1% corrosion	120	no change
metal inlet/outlet port	1-120	corrosion at soldered joints after 1 hr, increasing over time	120	no change
metal nut with metal-metal binding adhesive	1-120	corrosion at 15 min, increasing over time	8-120	corrosion at 24 hrs

Example 3

Electrochemically activated solutions including the compositions were prepared according to the formulations given in Table 3. pH, free chlorine concentration, and surface tension were measured. The three formulations listed in Table 3 proved to be effective.

Table 3

Formula	pH	Free Chlorine ppm.	Surface Tension dyne/cm.
1. DSP 0.3404 g/l MSP 0.0550 g/l HMP 0.0238 g/l 40S 0.0570 g/l Gen 0.0400 g/l	7.82	285	28.7
2. DSP 4.766 g/l MSP 0.400 g/l HMP 0.300 g/l Gen 0.400 g/l	7.73	273	28.0
3. DSP 5.7192 g/l MSP 0.700 g/l HMP 0.396 g/l Gen 0.400 g/l 40S 0.057 g/l	7.86	272	28.3

DSP = disodium phosphate
MSP = monosodium phosphate
HMP = hexametaphosphate
Gen = Genapol (fatty alcohol polyglycol ether)
40S = Cobratec 40S (sodium benzotriazole, 40 wt.%)

Having thus described the preferred embodiment, the invention is now claimed to be:

1. A composition for minimizing corrosivity and improving penetration of an electrochemically activated sterilizing or disinfecting solution without appreciably lowering the rate of kill of microorganisms by the solution, the composition characterized by:

a buffering system for buffering the pH of the electrochemically activated solution to a pH of between about 5.0 and about 9.0;

a corrosion inhibitor;

a non-ionic surfactant which is stable in the electrochemically activated solution; and

a chelator.

2. The composition of claim 1, further characterized by:

the buffering system being selected from the group consisting of:

mono-alkali metal phosphates, di-alkali metal phosphates, hexametaphosphates, sodium sulfate, and combinations thereof.

3. The composition of claim 2, further characterized by:

the buffering system further including 0.01-5% by weight tripolyphosphates.

4. The composition of either one of claims 2 and 3, further characterized by the buffering system including:

0.01-0.5% by weight monosodium phosphate and at least one of:

i) 0.01-5% by weight disodium phosphate, and

ii) 0.01-5% by weight sodium hexametaphosphate.

5. The composition of any one of preceding claims 1-

4, further characterized by:

the composition further including a non-ionic surfactant which lowers the surface tension of the electrochemically activated solution to 35 dynes/cm or below.

6. The composition of claim 5, further characterized by:

the non-ionic surfactant being selected from the group consisting of fatty alcohol polyglycol ethers, nonylphenoxypoly(ethyleneoxy) ethanol, ethoxylated polyoxypropylene, and combinations thereof.

7. The composition of any one of preceding claims 1-6, further characterized by:

the chelator being selected from the group consisting of hexametaphosphates, tripolyphosphates, sodium polyacrylates, sodium nitriloacetic acid, and combinations thereof.

8. The composition any one of preceding claims 1-7, further characterized by:

the composition further including at least one of:

i) a detergent, and

ii) a sequestering agent.

9. The composition of claim 1, further characterized by: the composition including:

0.01-5% by weight disodium phosphate,

0.01-0.5% by weight monosodium phosphate,

0.01-5% by weight hexametaphosphate, and

0.01-1.0 % by weight of a fatty alcohol polyglycol ether.

10. A method of sterilization/disinfection characterized by:

generating an electrochemically activated sterilant/

disinfectant solution which includes the composition of any one of claims 1-9; and,

immersing items to be sterilized/disinfected in the solution.

11. The method of claim 10, further characterized by:

the step of generating an electrochemically activated sterilant/disinfectant solution including:

separating the electrochemically activated solution with a membrane into anolyte and catholyte streams, the anolyte stream including an active chlorine species, and adding the composition to the anolyte stream; and,

the step of immersing items to be sterilized/disinfected in the solution including:

immersing the items in the anolyte stream.

12. The method of either one of claims 10 and 11, further characterized by:

the step of generating an electrochemically activated sterilant/disinfectant solution including generating a free chlorine concentration of between about 2 and about 2000 ppm.

13. An antimicrobial system comprising:

a source (12) of a salt solution, a generator (10) for generating an antimicrobial solution from the salt solution, the antimicrobial solution including active antimicrobial species, an inlet line (14), which fluidly connects the source of the salt solution to the generator, an antimicrobial vessel (24), an outlet line (22), which fluidly connects the generator to the antimicrobial vessel for transporting the antimicrobial solution to the vessel, the system characterized by:

a dispenser (26) for dispensing the composition of any one of claims 1-9 into one or more of the salt solution and the antimicrobial solution.

14. A sterilizing or disinfecting solution comprising free chlorine species and characterized by:

the solution further comprising the composition **of any one of claims 1-9.**

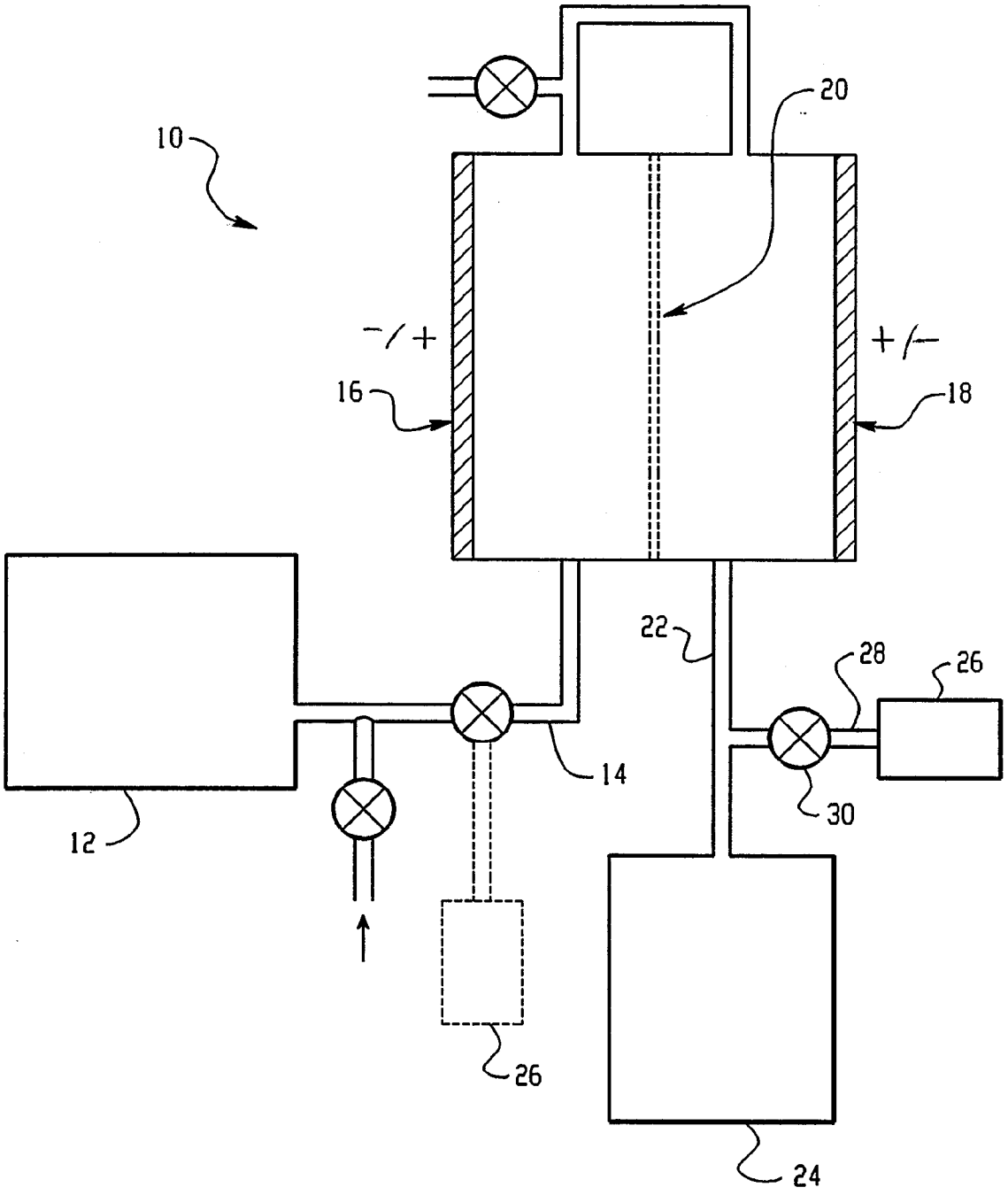

Fig. 1

INTERNATIONAL SEARCH REPORT

Int ional Application No
PCT/US 99/09474

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61L2/02 A61L2/18

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61L C23F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 357 238 A (STERIS CORP) 7 March 1990 (1990-03-07) page 3, line 34 - page 5, line 4 examples 1-4	1-9,13, 14
X	FR 2 550 946 A (PARANT BERNARD) 1 March 1985 (1985-03-01) the whole document	1,2,5-8, 10-12
X	GB 2 292 687 A (GREEN BRUCE PHILIP) 6 March 1996 (1996-03-06) page 3	1-3,5,7, 8
X	US 4 176 059 A (SUZUKI FUMIKO) 27 November 1979 (1979-11-27) claims	1-3,5-8

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
24 August 1999	02/09/1999

Name and mailing address of the ISA	Authorized officer
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Int tional Application No
PCT/US 99/09474

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